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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,377	07/18/2003	Thomas J. Jentsch	59572(46865)	9926

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Edwards & Angell, LLP  
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P.O. Box 55874  
Boston, MA 02205

EXAMINER
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HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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09/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/622,377

**Applicant(s)**

JENTSCH, THOMAS J.

**Examiner**

Joanne Hama, Ph.D.

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant filed a response to the Non-Final Action of February 27, 2007 on June 25, 2007. Claims 1-41 are cancelled. Claims 42-58 are amended.

Claims 42-67 are under consideration.

#### Withdrawn Rejection

##### *35 U.S.C. § 112, 1<sup>st</sup> parag., Enablement*

Applicant's arguments, see pages 9-11, filed June 25, 2007 have been fully considered and they are persuasive. Applicant indicates that the claims have been amended such that claimed cells require a genetic modification. The rejection of claims 42-67 is withdrawn.

##### *35 U.S.C. § 112, 2<sup>nd</sup> parag.*

Applicant's arguments, see pages 11-13, filed June 25, 2007, with respect to the rejection of claims 42-67 have been fully considered and are persuasive. Applicant has amended the claims to indicate that the protein is "functional." The rejection of claims 42-67 has been withdrawn.

##### *35 U.S.C. § 102*

Applicant's arguments, see pages 13-15, filed June 25, 2007, with respect to the rejection of

claims 42, 43 as being anticipated by Grant and Acosta, 1996;

claims 42-44 as being anticipated by Johnson-Muller and Gross, 1987;

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claims 48, 49 as being anticipated by Tamm et al., 1999;

claims 42-46 as being anticipated by Gupta et al., 1996;

claims 42-44, 50-53 as being anticipated by Lee et al., 1998;

have been fully considered and are persuasive. Applicant indicates that the claimed cells are now restricted to genetically modified cells. With regard to Applicant indicating that post-filing art (Mummery et al., Comes et al., Davies et al., and Kulka et al) was not published in time to be prior art in this case (Applicant's response, page 15), it is noted that the post-filing art was not used to reject the claims under 102. The post-filing art was used as evidence to show that artisans in the prior art have already isolated naturally occurring cells that fit the structural limitations of the claims filed November 22, 2006. Note also that in the enablement rejection (Office Action, February 27, 2007, page 6), that neither the art nor the specification has taught how to isolate naturally occurring cells. The 102 rejection further supports the fact that post-filing art was required to practice the claimed invention for naturally occurring cells.

The rejection of claims 42-46, 50-53 has been withdrawn.

### **New Rejections**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-67 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims is drawn to claiming a cell or a cell line. However, the claims end with a conclusion that cells, cell lines, membrane preparations, and cell vesicles are being claimed such that the metes and bounds of the claims cannot be determined. Should Applicant wish to claim membrane preparation or cell vesicle, it should be indicated in the preamble, so that the preamble and conclusion of the claim have the same scope.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42, 48, 50, 53, 54, 59-67 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Maher et al., U.S. Patent 6,686,193, patented February 3, 2004.

Maher et al. teach a method that measures membrane potential in cells. The method comprises expressing a target ion channel on a population of cells, introducing a candidate drug, and measuring the changes in membrane potential of the cells before and after drug treatment (Maher et al., col. 3, under "Summary of the Invention"). In addition to using primary cell lines that express endogenous ion channels, cells having no (or very low) detectable endogenous expression of ion channels can be transfected with nucleic acid constructs comprising nucleic acid sequences encoding ion channels (Maher et al., col. 29-31, under "6. VI Expression of Ion Channels"; with specific reference to chloride channels, see col. 47, 3<sup>rd</sup> parag.). Maher et al. teach that in addition to transient transfection, the transgene constructs can be stably integrated

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into the cell (Maher et al., col. 31, 2<sup>nd</sup> parag. and 5<sup>th</sup> parag.). Maher et al. indicate that chloride channels are envisioned to be expressed from transgene constructs (Maher et al., col. 31, reference to Table 3, 2<sup>nd</sup> parag. and col. 46-48). To aid in the measurement of changes in transmembrane potential, transmembrane potential dyes can be used (Maher et al., col. 47, 3<sup>rd</sup> parag.).

Maher et al. teach that 9 chloride channels were known (Maher et al., Table 3).

The claims are rejected under 35 USC 103 as being unpatentable over Maher et al. Maher et al. teach a method used to measure membrane potential cells. The method has applications in screening for drugs that affect the membrane potential in cells that express an ion channel. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of using Maher et al.'s method in a screen for drugs that modulate ion channels. In addition to this, Maher et al. teach that ClC-3, 4, 6, and 7 are each of a finite number of chloride channels that can be used in a method to screen for drugs that modulate them. Furthermore, Maher et al. teaches that transgene constructs can be used to express each of the channels in cells that have no (or very low) detectable endogenous expression of ion channels. Thus, it would have been obvious to an ordinary artisan to express a single chloride channel in a cell with no (or very low) detectable endogenous ion channel expression in an attempt to use Maher et al.'s method of screening for compounds that modulate the activity of each chloride channel, as a person of ordinary skill has good reason to pursue to known options within his or her technical grasp. Because the cells, as claimed, have the properties predicted by the prior art, it would have been obvious to make cells expressing one chloride channel.

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It is noted that Maher et al. is readable on the claims as they encompass cells that express one chloride channel.

### ***Conclusion***

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Joanne Hama  
Art Unit 1632

*/Anne Marie S. Wehbe/*  
Primary Examiner, A.U. 1633